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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Raju Kucherlapati et al.

Serial No.: 08/031,801 Group Art Unit: 1804

Filed: March 15, 1993 Examiner: S. Ziska

For: GENERATION OF XENOGENEIC ANTIBODIES Group Director: John Doll

Atty Docket No.: 7639-031-999

REQUEST FOR EXPEDITED NOTICE OF ALLOWANCE AND ISSUANCE OF PATENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants hereby request expedited mailing of the formal Notice of Allowance and issuance of a patent in connection with the above-captioned patent application.

By way of background, the PTO Examiner handling the above-captioned patent application, Suzanne E. Ziska, mailed a communication on March 1, 1996 suspending ex parte prosecution of the application for six (6) months for reason of a potential interference.

On April 30, 1996, Examiner Suzanne E. Ziska mailed a Notice of Allowability, an Examiner Interview Summary Record (recording an Interview of April 24, 1996), and an Examiner's Amendment. As such, the application was in condition for allowance, and the formal Notice of

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being filed with the United States Patent and Trademark Office by facsimile transmission on August 7, 1996 (date) to facsimile telephone number 703/305-7230

Albert D. Halluin 25,227 (Reg. No.)

PEMP-60151.1

Allowance could be mailed but for the potential interference.

It is the Applicants' understanding and belief that the potential interference would be between Applicants' instant patent application and an application (or a progeny thereof) to Kay and Lunberg, assigned to GenPharm International, U.S. Serial No. 07/574,748, filed August 29, 1990. Applicants are aware of U.S. Serial No. 07/574,748 from the publicly available priority documents referenced in PCT/US/91/06185, published as PCT WO 92/03918, published March 19, 1992. A copy of the cover page of the published PCT WO 92/03918 document is attached. Assuming that these are the conflicting patent applications, Applicants' instant patent application has priority dates of January 12, 1990, November 8, 1990, and July 24, 1992. Applicants' earliest priority date is more than six (6) months earlier than the purported conflicting patent application priority date. MPEP §2303 states in part:

> Interferences will not be declared between pending applications if there is a difference of more than 3 months in the effective filing dates of the oldest and the next oldest applications, in the case of inventions of a simple character, or a difference of more than 6 months in the effective filing dates of the applications in other cases, except in exceptional situations, as determined and approved by the group director. (Emphasis added)

Applicants' files do not indicate that the group director approved of proceeding with an interference. Therefore, if the above-captioned patent application file has been forwarded to the PTO Board of Patent Appeals and Interferences, the application should be remanded to the attention of the group director of Group 1800 to determine if this is an exceptional case warranting the declaration of an interference. Applicants are of the

view that there are no circumstances as enumerated in MPEP §2303 which warrant this being an exceptional situation.

Accordingly, the instant application should be formally allowed, the Base Issue Fee mailed to Applicants and expedited issuance upon payment of the Base Issue Fee should be processed. Such action is earnestly solicited.

Respectfully submitted,

Date 8/7/96

Albert P. Halluin (Reg. No. 25,227)

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Enclosure

COMMON OWNERSHIP

Where applications by different inventive entities but of common ownership claim the same subject matter or subject matter that is not patentably different:

I. Interference therebetween is normally not instituted since there is no conflict of interest. Elimination of conflicting claims from all except one case should usually be required, 37 CFR 1.78(c). The common assignee must determine the application in which the conflicting claims are properly placed. Treatment by rejection is set forth in MPEP § 804.03.

II. Where an interference with a third party is found to exist, the commonly owned application having the earliest effective filing date will be placed in interference with the third party. The common assignee may move during the interference under 37 CFR 1.633(d) to substitute the other commonly owned application, if desired.

2303 Interference Between Applications

37 CFR 1.603. Interference between applications; subject matter of the interference.

Before an interference is declared between two or more applications, the examiner must be of the opinion that there is interfering subject matter claimed in the applications which is patentable to each applicant subject to a judgment in the interference. The interfering subject matter shall be defined by one or more counts. Each count shall define a separate patentable invention. Each application must contain, or be amended to contain, at least one claim which corresponds to each count. All claims in the applications which define the same patentable invention as a count shall be designated to correspond to the count.

Where two or more applications are found to be claiming the same patentable invention, they may be put in interference, dependent on the status of the respective applications and the difference between their filing dates. One of the applications should be in condition for allowance. Unusual circumstances may justify an exception to this if the approval of the group director is obtained.

Interferences will not be declared between pending applications if there is a difference of more than 3 months in the effective filing dates of the oldest and the next oldest applications, in the case of inventions of a simple character, or a difference of more than 6 months in the effective filing dates of the applications in other cases, except in exceptional situations, as determined and approved by the group director. One such exceptional situation would be where one application has the earliest effective filing date based on foreign priority and the other application has the earliest effective United States filing date. If an interference is declared, all applications having the interfering subject matter should be included.

Before taking any steps looking to the formation of an interference, it is essential that the examiner make certain that each of the prospective parties is claiming the same patentable invention (as defined in 37 CFR 1.601(n)) and that at least one claim of each party corresponds to each count of the interference and is clearly readable upon the disclosure of that party and allowable in its application.

It is to be noted that while the claims of two or more applicants may not be identical, yet if directed to the same patentable invention, an interference exists. But mere disclosure by an applicant of an invention which he or she is not claiming does not afford a ground for suggesting to that applicant a claim for the said invention based upon claims from another application that is claiming the invention. The intention of the parties to claim the same patentable invention, as expressed in the summary of the invention or elsewhere in the disclosure or in the claims, is an essential in every instance.

Where the subject matter found to be allowable in one application is disclosed and claimed in another application, but the claims therein to such subject matter are either nonelected or subject to election, the question of interference should be considered. The requirement of 37 CFR 1.601(i) that the conflicting applications shall contain claims for the same patentable invention should be interpreted as meaning generally that the conflicting claimed subject matter is sufficiently supported in each application and is patentable to each applicant over the prior art. The statutory requirement of first inventorship is of transcendent importance and every effort should be made to avoid the improvident issuance of a patent where there is an adverse claimant.

Following are illustrative situations where the examiner should take action toward instituting interference:

A. Application filed with claims to divisible inventions I and II. Before action requiring restriction is made, examiner discovers another case having claims to invention I.

The situation is not altered by the fact that a requirement for restriction had actually been made but had not been responded to. Nor is the situation materially different if an election of noninterfering subject matter had been made without traverse but no action given on the merits of the elected invention.

B. Application filed with claims to divisible inventions I and II and in response to a requirement for restriction, applicant traverses the same and elects invention I. Examiner gives an action on the merits of I. Examiner subsequently finds an application to another containing allowed claims to invention II and which is ready for issue.

The situation is not altered by the fact that the election is made without traverse and the nonelected claims possibly cancelled.

PCT W D INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

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(60) Parent Application or Grant
(63) Related by Continuation
US 574,748 (CIP)
Filed on 29 August 1990 (29.08.90)

(71) Applicant *(for all designated States except US)*: GENPHARM INTERNATIONAL INC. [US/US]; 2375 Garcia Avenue, Mountain View, CA 94043 (US).

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(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: TRANSGENIC NON-HUMAN ANIMALS CAPABLE OF PRODUCING HETEROLOGOUS ANTIBODIES

(57) Abstract

The invention relates to transgenic non-human animals capable of producing heterologous antibodies, *i.e.*, antibodies encoded by immunoglobulin heavy and light chain genes not normally found in the genome of that species of non-human animal. In one aspect of the invention, transgenes encoding unrearranged heterologous human immunoglobulin heavy and light chains are introduced into a non-human animal thereby forming a transgenic animal capable of producing antibodies encoded by human immunoglobulin genes. Such heterologous human antibodies are produced in B-cells which are thereafter immortalized, *e.g.*, by fusing with an immortalizing cell line such as a myeloma or by manipulating such B-cells by other techniques to perpetuate a cell line capable of producing a monoclonal heterologous antibody. The invention also relates to heavy and light chain immunoglobulin transgenes for making such transgenic non-human animals as well as methods and vectors for disrupting endogenous immunoglobulin loci in the transgenic animal. The invention also includes methods to generate a synthetic immunoglobulin variable region gene segment repertoire used in transgene construction and methods to induce heterologous antibody production using animals containing heterologous rearranged or unrearranged heavy and light chain immunoglobulin transgenes.

FACSIMILE TRANSMISSION RECORD/COVER SHEET 30

TO

Name Mel Cashion

Title Interference Administrator

Dept.

Company or Firm U.S. PTO

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Date August 9, 1996 Menlo Park, CA. Time 1 PM

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Client Cell Genesys File # 7639-0031-999

If there is a problem with this transmittal, please telephone us at (415) 926 - 7457 and ask for Alice Tam.

COMMENTS

Dear Mr. Cashion,

Please call me at 415/854-3660 as soon as possible so that we can avoid unnecessary burden and expense to the PTO and my client with respect to this possible interference. Thanks.